# BEFORE THE BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

In the Matter of the Accusation Against:

Case No. 5605 OAH No. 2016050394

SAFEWAY PHARMACY INC.<sup>1</sup> d.b.a. Safeway Pharmacy #4905 6100 Hellyer Avenue, Suite 100 San Jose, California 95138

Original Permit No. PHY 52537

SAFEWAY PHARMACY INC. d.b.a. Safeway Pharmacy #4526 <sup>2</sup> 255 Second Street Los Altos, California 94022

Original Permit No. PHY 51192,

Respondents.

### **DECISION AND ORDER**

The attached Stipulated Surrender of License and Order is hereby adopted by the Board of Pharmacy, Department of Consumer Affairs, as its Decision in this matter.

This Decision shall become effective at 5:00 p.m. on December 22, 2016.

It is so ORDERED November 22, 2016.

BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA

 $\mathbf{B}\mathbf{y}$ 

Amy Gutierrez, Pharm.D. Board President

The accusation is against "Safeway Pharmacy Inc."; however, the incorporated entity is "Safeway Inc."

The accusation lists the business name as "Safeway Pharmacy #4526; however, the business name is "Safeway #4526."

1	KAMALA D. HARRIS	
2	Attorney General of California DIANN SOKOLOFF	
3	Supervising Deputy Attorney General GREGORY TUSS	
	Deputy Attorney General	
4	State Bar No. 200659 1515 Clay Street, 20th Floor	
5	P.O. Box 70550 Oakland, CA 94612-0550	
6	Telephone: (510) 622-2143 Facsimile: (510) 622-2270	
7	Attorneys for Complainant	
8	BEFORI	
9	BOARD OF PHARMACY DEPARTMENT OF CONSUMER AFFAIRS	
10	STATE OF CA	ALIFORNIA
11	In the Matter of the Accusation Against:	Case No. 5605
12	SAFEWAY PHARMACY INC.1	OAH No. 2016050394
13	6100 Hellyer Avenue, Suite 100	STIPULATED SURRENDER AND ORDER
14	San Jose, California 95138	
15	Original Permit No. PHY 52537	
16	SAFEWAY PHARMACY INC. d.b.a. Safeway Pharmacy #4526 <sup>2</sup>	
17	255 Second Street Los Altos, California 94022	
18	Original Permit No. PHY 51192,	
19	Respondents.	
20	itosponaciius.	•
21		
22	IT IS STIPULATED AND AGREED by ar	nd between the parties to the above-entitled
23	proceedings that the following matters are true:	sa derived in parties to the doors chithed
24	///	
25		
26	The accusation is against "Safeway	Pharmacy Inc."; however, the incorporated
	entity is "Safeway Inc." This Stipulated Surrender	will use the correct name "Safeway Inc."
27 28	The accusation lists the business name the business name is "Safeway #4526." This Stipu "Safeway #4526."	me as "Safeway Pharmacy #4526"; however, ilated Surrender will use the correct name
-	1	

#### **PARTIES**

- 1. Complainant Virginia Herold is the Executive Officer of the Board of Pharmacy (board), Department of Consumer Affairs. She brought this action solely in her official capacity and is represented in this matter by Kamala D. Harris, Attorney General of the State of California, and by Gregory Tuss, Deputy Attorney General.
- 2. Respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905 and Safeway #4526, is represented in this proceeding by attorney Craig O'Loughlin and Alissa Brice Castaneda, whose address is Two North Central Avenue, Phoenix, AZ 95004.
- 3. On December 3, 2014, the board issued Original Permit No. PHY 52537 to respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905. Original Permit No. PHY 52537 was cancelled on March 6, 2015.
- 4. On December 13, 2012, the board issued Original Permit No. PHY 51192 to respondent Safeway Inc., d.b.a. Safeway #4526. Original Permit No. PHY 51192 was cancelled on January 29, 2015.

#### **JURISDICTION**

5. Accusation No. 5605 was filed before the board and is currently pending against respondents. The accusation and all other statutorily required documents were properly served on respondents on January 21, 2016. Respondents timely filed their notices of defense contesting the accusation. A copy of Accusation No. 5605 is attached as exhibit 1 and incorporated by reference.

#### ADVISEMENT AND WAIVERS

- 6. Respondents have carefully read, fully discussed with counsel, and understand the charges and allegations in Accusation No. 5605. Respondents have also carefully read, fully discussed with counsel, and understand the effects of this Stipulated Surrender of License and Order.
- 7. Respondents are fully aware of their legal rights in this matter, including the right to a hearing on the charges and allegations in the accusation; the right to confront and cross-examine the witnesses against them; the right to present evidence and to testify on their own

behalf; the right to the issuance of subpoenas to compel the attendance of witnesses and the production of documents; the right to reconsideration and court review of an adverse decision; and all other rights accorded by the California Administrative Procedure Act and other applicable laws.

8. Respondents voluntarily, knowingly, and intelligently waive and give up each and every right set forth above.

#### CULPABILITY

- 9. Respondents understand and agree that the charges and allegations in Accusation No. 5605, if proven at a hearing, constitute cause for imposing discipline upon their Original Permit No. PHY 52537 and Original Permit No. PHY 51192.
- 10. For the purpose of resolving the accusation without the expense and uncertainty of further proceedings, respondents agree that, at a hearing, complainant could establish a factual basis for the charges in the accusation, and that respondents give up their right to contest those charges.
- 11. Respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905, agrees that cause exists for discipline of its Original Permit No. PHY 52537 and surrenders Original Permit No. PHY 52537 for the board's formal acceptance.
- 12. Respondent Safeway Inc., d.b.a. Safeway #4526, agrees that cause exists for discipline of its Original Permit No. PHY 51192 and surrenders its Original Permit No. PHY 51192 for the board's formal acceptance.
- 13. Respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905, understands that by signing this stipulation, respondent enables the board to issue an order accepting the surrender of its Original Permit No. PHY 52537 without further process.
- 14. Respondent Safeway Inc., d.b.a. Safeway #4526, understands that by signing this stipulation, respondent enables the board to issue an order accepting the surrender of its Original Permit No. PHY 51192 without further process.

#### RESERVATION

15. The admissions made by respondents in this stipulation are only for the purposes

of this proceeding, or any other proceedings in which the Board of Pharmacy or other professional licensing agency is involved, and shall not be admissible in any other criminal or civil proceeding.

#### **CONTINGENCY**

- 16. This stipulation shall be subject to approval by the board. Respondents understand and agree that counsel for complainant and the staff of the board may communicate directly with the board regarding this stipulation and surrender, without notice to or participation by respondents or their counsel. By signing the stipulation, respondents understand and agree that they may not withdraw their agreement or seek to rescind the stipulation prior to the time the board considers and acts upon it. If the board fails to adopt this stipulation as its Decision and Order, the Stipulated Surrender and Order shall be of no force or effect, except for this paragraph; it shall be inadmissible in any legal action between the parties; and the board shall not be disqualified from further action by having considered this matter.
- 17. The parties understand and agree that portable document format (PDF) and facsimile copies of this Stipulated Surrender of License and Order, including PDF and facsimile signatures, shall have the same force and effect as the originals.
- 18. This Stipulated Surrender of License and Order is intended by the parties to be an integrated writing representing the complete, final, and exclusive embodiment of their agreement. It supersedes any and all prior or contemporaneous agreements, understandings, discussions, negotiations, and commitments (written or oral). This Stipulated Surrender of License and Order may not be altered, amended, modified, supplemented, or otherwise changed except by a writing executed by an authorized representative of each of the parties.
- 19. In consideration of the foregoing admissions and stipulations, the parties agree that the board may, without further notice or formal proceeding, issue and enter the following Order:

#### ORDER

IT IS ORDERED that Original Permit No. PHY 52537 and Original Permit No. PHY 51192 issued to respondent Safeway Inc., d.b.a. Safeway Pharmacy #4905 and Safeway #4526, are surrendered and accepted by the Board of Pharmacy.

- 1. The surrender of respondents' Original Permit No. PHY 52537 and Original Permit No. PHY 51192 and the acceptance of these surrendered licenses by the board shall constitute the imposition of discipline against respondents. This stipulation constitutes a record of the discipline and shall become a part of respondents' license histories with the Board of Pharmacy.
- 2. Respondents shall lose all rights and privileges as pharmacies in California as of the effective date of the board's Decision and Order.
- 3. Respondents shall cause to be delivered to the board their pocket licenses and, if they were issued, their wall certificates on or before the effective date of the Decision and Order.
- 4. If respondents ever apply for licensure or petitions for reinstatement in the State of California, the board shall treat it as a new application for licensure. Respondents may not reapply to the board for reinstatement of their revoked licenses for three years from the effective date of this decision. Respondents must comply with all the laws, regulations and procedures for licensure in effect at the time the application or petition is filed, and all of the charges and allegations contained in Accusation No. 5605 shall be deemed to be true, correct and admitted by respondents when the board determines whether to grant or deny the application or petition.
- 5. Respondents stipulate that should they apply for any license from the board on or after the effective date of this decision, investigation and prosecution costs in the amount of \$10,766.75 shall be paid to the board prior to issuance of the license. Respondents are responsible for these costs jointly and severally with respondents John Vincent Castaldo, Karen Lyn Muir, and Christine Moheb Stephanos, who are also named in Accusation No. 5605, to the extent that each respondent is held responsible for those costs by a settlement agreement or final adjudication of the accusation.
- 6. If respondents should ever apply or reapply for a new license or certification, or petition for reinstatement of a license, by any other health care licensing agency in the State of California, all of the charges and allegations contained in Accusation No. 5605 shall be deemed to be true, correct, and admitted by respondents for the purpose of any statement of issues or any other proceeding seeking to deny or restrict licensure.

#### ACCEPTANCE 1 I have carefully read the above Stipulated Surrender of License and Order and have fully 2 discussed it with my attorneys, Craig O'Loughlin and Alissa Brice Castaneda. I understand the 3 stipulation and the effect it will have on Original Permit No. PHY 52537 and Original Permit No. 4 PHY 51192. I enter into this Stipulated Surrender of License and Order voluntarily, knowingly, 5 6 and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy. 7 DATED: 8 SAFEWAY INC. 9 d.b.a. Safeway Pharmacy #4905 and Safeway 10 Respondent 11 I have read and fully discussed with respondent Safeway Inc., d.b.a. Safeway Pharmacy 12 #4905 and Safeway #4526, the terms and conditions and other matters contained in this Stipulated 13 Surrender of License and Order. I approve its form and content. 14 DATED: CRAIG O'LOUGHLIN 15 ALISSA BRICE CASTANEDA 16 Attorneys for Respondent 17 ENDORSEMENT 18 This Stipulated Surrender of License and Order is submitted for consideration by the 19 Board of Pharmacy of the Department of Consumer Affairs. 20 Dated: Respectfully submitted, 21 KAMALA D. HARRIS 22 Attorney General of California DIANN SOKOLOFF 23 Supervising Deputy Attorney General 24 25 **GREGORY TUSS** 26 Deputy Attorney General Attorneys for Complainant

6

27

28

SF2015402803 Safeway Surrender.doc

#### ACCEPTANCE

I have carefully read the above Stipulated Surrender of License and Order and have fully discussed it with my attorneys, Craig O'Loughlin and Alissa Brice Castaneda. I understand the stipulation and the effect it will have on Original Permit No. PHY 52537 and Original Permit No. PHY 51192. Lenter into this Stipulated Surrender of License and Order voluntarily, knowingly, and intelligently, and agree to be bound by the Decision and Order of the Board of Pharmacy.

d.b.a. Safeway Pharmacy #4905 and Safeway #4526 Respondent I have read and fully discussed with respondent Safeway Inc., d.b.a. Safeway Pharmacy

#4905 and Safeway #4526, the terms and conditions and other matters contained in this Stipulated Surrender of License and Order. I approve its form and content,

DATED:

CRAIG O'LOUGHLIN ALISSA BRICE CASTANEDA Attorneys for Respondent

#### ENDORSEMENT

This Stipulated Surrender of License and Order is submitted for consideration by the Board of Pharmacy of the Department of Consumer Affairs.

Dated: 10.17.16

1

2

3

5

б

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

Respectfully submitted,

Kamala D. Harris Attorney General of California DIANN ŞOKOLOFF Supervising Deputy Attorney General

Deputy Attorney/General Attorneys for Complainant

SF2015402803 Safeway Surrender.doc

## Exhibit 1

Accusation No. 5605

	\	•	
1	KAMALA D. HARRIS		
2	Attorney General of California DIANN SOKOLOFF		
3	Supervising Deputy Attorney General GREGORY TUSS		
4	Deputy Attorney General State Bar No. 200659		
5	1515 Clay Street, 20th Floor Post Office Box 70550		
6	Oakland, California 94612-0550		
	Telephone: (510) 622-2143 Facsimile: (510) 622-2270		
7	Attorneys for Complainant		
8	BEFORE THE BOARD OF PHARMACY		
9	DEPARTMENT OF CONSUMER AFFAIRS STATE OF CALIFORNIA		
10		7	
11	In the Matter of the Accusation Against:	Case No. 5605	
12	SAFEWAY PHARMACY INC.	ACCUSATION	
13	d.b.a. Safeway Pharmacy #4905 6100 Hellyer Avenue, Suite 100 San Jose, California 95138		
14	Original Permit No. PHY 52537		
15	Original Permit No. PHY 53416,		
16	SAFEWAY PHARMACY INC.		
17	d.b.a. Safeway Pharmacy #4526 255 Second Street		
18	Los Altos, California 94022		
19	Original Permit No. PHY 51192,	,	
20	JOHN VINCENT CASTALDO 23750 Hutchinson Road Los Gatos, California 95033		
21		,	
22	Original Pharmacist License No. RPH 31324,		
23	KAREN LYN MUIR 156 Dunsmuir Way		
24	Menlo Park, California 94025		
25	Original Pharmacist License No. RPH 39228,		
26	and ·		
27			
28			
	1		
ll ll			

ACCUSATION (SAFEWAY, CASTALDO, MUIR, STEPHANOS)

January 31, 2016, unless renewed.

1

11

14

15

16

18

19

20

21

22

23

24

25

26

27

28

JURISDICTION

П.

"(3) Purchase, trade, sell, or transfer dangerous drugs that the person knew or reasonably should have known were misbranded, as defined in Section 111335 of the Health and Safety Code."

#### 12. Section 4301 states in part:

"The board shall take action against any holder of a license who is guilty of unprofessional conduct or whose license has been procured by fraud or misrepresentation or issued by mistake. Unprofessional conduct shall include, but is not limited to, any of the following:

. . .

- "(o) Violating or attempting to violate, directly or indirectly, or assisting in or abetting the violation of or conspiring to violate any provision or term of this chapter or of the applicable federal and state laws and regulations governing pharmacy, including regulations established by the board or by any other state or federal regulatory agency."
  - 13. Section 4306.5 states in part:

"Unprofessional conduct for a pharmacist may include any of the following:

- "(b) Acts or omissions that involve, in whole or in part, the failure to exercise or implement his or her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of controlled substances, dangerous drugs, or dangerous devices, or with regard to the provision of services."
  - 14. Health and Safety Code section 111335 states:

"Any drug or device is misbranded if its labeling or packaging does not conform to the requirements of Chapter 4 (commencing with Section 110290)."

15. Health and Safety Code section 111397 subdivision (a), states:

"Any foreign dangerous drug that is not approved by the United States Food and Drug Administration or that is obtained outside of the licensed supply chain regulated by the United States Food and Drug Administration, California State Board of Pharmacy, or State Department

of Public Health is misbranded."

16. Health and Safety Code section 111400 states:

"Any drug or device is misbranded if it is dangerous to health when used in the dosage, or with the frequency or duration prescribed, recommended, or suggested in its labeling."

17. Health and Safety Code section 111440 states:

"It is unlawful for any person to manufacture, sell, deliver, hold, or offer for sale any drug or device that is misbranded."

18. California Code of Regulations, title 16, section 1735,3, subdivision (a), states in part:

"For each compounded drug product, the pharmacy records shall include:

"(4) The identity of the pharmacist reviewing the final drug product."

#### IV. COST RECOVERY

19. Section 125.3, subdivision (a), states:

"Except as otherwise provided by law, in any order issued in resolution of a disciplinary proceeding before any board within the department or before the Osteopathic Medical Board, upon request of the entity bringing the proceedings, the administrative law judge may direct a licentiate found to have committed a violation or violations of the licensing act to pay a sum not to exceed the reasonable costs of the investigation and enforcement of the case."

#### V. DRUGS

20. Domperidone is an anti-dopaminergic drug which acts as an antiemetic and prokinetic agent. It is used relieve nausea and vomiting, and to increase lactation. It is a dangerous drug under Business and Professions Code section 4022. Although the United States Food and Drug Administration (FDA) may approve an application to use domperidone as an investigational new drug in treating various gastrointestinal conditions, the use of domperidone is not approved in the United States for any indication. The FDA has determined that any products containing domperidone are unapproved new drugs and misbranded. Consequently, any product containing domperidone violates the Federal Food, Drug, and Cosmetic Act (21 U.S.C. § 301 et

7

8

9

10

11

12

13

14

15

16

17

18

19

20

21

22

23

24

25

26

27

28

#### FACTUAL BACKGROUND

21. On April 8, 2015, the Board inspected respondent Safeway at its present address of 3 record. The inspectors found a 500 gram bulk powder container of domperidone with an 4 expiration date of January 30, 2018. The container stated "NOT FOR HUMAN USE NOT FOR 5 US[E] IN FOOD[-]PRODUCING ANIMALS." Respondent Castaldo, the pharmacist-in-charge 6 at respondent Safeway, said that Safeway had been compounding domperidone. He said that the domperidone manufacturer told him that the FDA told the manufacturer to put the warning on the label but it is safe to use on humans. Respondent Castaldo told the inspectors that the Professional Compounding Centers of America said to keep compounding with domperidone until "somebody shuts you down." He said that nevertheless respondent Safeway had stopped compounding domperidone about a month before the inspection. The inspectors embargoed the domperidone.

22. Worksheets show the following instances of domperidone compounding at respondent Safeway. All worksheets list respondent Castaldo as the pharmacist.

	a)	7/21/14	600 10mg capsules	Checked by Muir
	b)	10/8/14	300 30mg capsules	Checked by Muir
	c)	10/27/14	300 10mg capsules	Checked by Castaldo
	d)	11/13/14	300 10mg capsules	Checked by Muir
	e)	12/11/14	300 10mg capsules	Checked by [unknown]
	f)	1/12/15	300 10mg capsules	Checked by [blank]
	g)	2/6/15	300 20mg capsules	Checked by [blank]
	h)	2/18/15	300 10mg capsules	Checked by [blank]
	i)	3/4/15	300 20mg capsules	Checked by [blank]

23. Pharmacy records show respondent Safeway dispensed approximately 423 prescriptions for domperidone totaling approximately 45,898 capsules ranging from 5mg to

Instances a) through e) are attributable to respondent Safeway PHY 51192, f) through h) to respondent Safeway PHY 52537, and i) to respondent Safeway PHY 53416.

28

40mg. Approximately 374 of these prescriptions totaling approximately 28,693 capsules were
dispensed by respondent Safeway PHY 51192, approximately 39 prescriptions totaling
approximately 16,263 capsules by respondent Safeway PHY 52537, and approximately 10
prescriptions totaling approximately 942 capsules by respondent Safeway PHY 53416.

Respondent Castaldo dispensed and verified approximately 190 prescriptions for domperidone totaling approximately 21,360 capsules. Respondent Muir dispensed and verified approximately 161 prescriptions totaling approximately 16.813 capsules. Respondent Stephanos dispensed and verified 72 prescriptions totaling approximately 7,725 capsules.

Unprofessional Conduct - Manufacturing Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3), Health and Safety Code section 111440

- The allegations of paragraphs 20-24 are realleged and incorporated by reference as
- Respondent Safeway has subjected its Original Permit No. PHY 51192 to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code. §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 28,693 domperidone capsules were compounded at respondent Safeway PHY 51192.

Unprofessional Conduct - Selling, Transferring, and Delivering Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3), Health and Safety Code section 111440

- The allegations of paragraphs 20-24 are realleged and incorporated by reference as
- Respondent Safeway has subjected its Original Permit No. PHY 51192 to discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent Safeway PHY 51192 dispensed approximately 374 prescriptions for domperidone

1	totaling approximately 28,693 capsules.	
2	B. Safeway PHY 52537	
3	Third Cause for Discipline Unprofessional Conduct Manufacturing Misbranded Drugs	
4	Business and Professions Code sections 4301, subdivision (0), 4169, subdivision (a)(3),  Health and Safety Code section 111440	
5	Leanin and Salety Code section 111440	
6	29. The allegations of paragraphs 20-24 are realleged and incorporated by reference as	
7	if fully set forth.	
8	30. Respondent Safeway has subjected its Original Permit No. PHY 52537 to	
9	discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code	
10	§§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 16,263	
11	domperidone capsules were compounded at respondent Safeway PHY 52537.	
12	Unprofessional Conduct - Selling, Transferring, and Delivering Misbranded Drugs	
13		
14	xxouten and patoty Code Section 111440	
15	31. The allegations of paragraphs 20-24 are realleged and incorporated by reference as	
16	if fully set forth.	
17	32. Respondent Safeway has subjected its Original Permit No. PHY 52537 to	
18	discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs	
19	(Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).	
20	Respondent Safeway PHY 52537 dispensed approximately 39 prescriptions for domperidone	
21	totaling approximately 16,263 capsules,	
22	C. Safeway PHY 53416	
23	Fifth Cause for Discipline Unprofessional Conduct – Manufacturing Misbranded Drugs	
.4	Business and Professions Code sections 4301, subdivision (a), 4169, subdivision (a)(3), Health and Safety Code section 111440	
25		
26	33. The allegations of paragraphs 20-24 are realleged and incorporated by reference as	
27	if fully set forth.	
28	34. Respondent Safeway has subjected its Original Permit No. PHY 53416 to	
	8	

1	discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code,			
2	§§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Approximately 942			
3	domperidone capsules were compounded at respondent Safeway PHY 53416.			
4 5	Sixth Cause for Discipline Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs			
6	Business and Professions Code sections 4301, subdivision (0), 4169, subdivision (a)(3), Health and Safety Code section 111440			
7	35. The allegations of paragraphs 20-24 are realleged and incorporated by reference as			
8	if fully set forth.			
9	36. Respondent Safeway has subjected its Original Permit No. PHY 53416 to			
10	discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs			
11	(Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440).			
12	Respondent Safeway PHY 53416 dispensed approximately 10 prescriptions for domperidone			
13	totaling approximately 942 capsules.			
14	D. Castaldo			
15 16 17	Seventh Cause for Discipline Unprofessional Conduct – Manufacturing Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3), Health and Safety Code section 111440			
18				
10	37. The allegations of paragraphs 20-24 are realleged and incorporated by reference as			
	37. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.			
19	Company of the second of the s			
19 20	if fully set forth.			
19 2 <b>0</b> 21	if fully set forth.  38. Respondent Castaldo has subjected his original pharmacist license to discipline for			
19 20 21 22 23	if fully set forth.  38. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301,			
19 20 21 22	if fully set forth.  38. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded			
19   220   221   222   233   224   225	if fully set forth.  38. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded domperidone.  Eighth Cause for Discipline  Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3),			
19 20 21 22 22 23 24 25	if fully set forth.  38. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of manufacturing misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent compounded domperidone.  Eighth Cause for Discipline Unprofessional Conduct – Selling, Transferring, and Delivering Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3), Health and Safety Code section 111440			

40. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus. & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent Castaldo dispensed and verified approximately 190 prescriptions for domperidone totaling approximately 21,360 capsules.

Ninth Cause for Discipline
Unprofessional Conduct – Failure to Exercise or Implement Best Professional Judgment or
Corresponding Responsibility
Business and Professions Code sections 4301, 4306.5, subdivision (b)

- 41. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.
- 42. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of failing to exercise or implement his best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs (Bus. & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent compounded, dispensed, and verified prescriptions for domperidone.

Tenth Cause for Discipline
Unprofessional Conduct – Failure to Identify Identity of Reviewing Pharmacist
Business and Professions Code section 4301, subdivision (o),
California Code of Regulations, title 16, section 1735.3, subdivision (a)

- 43. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.
- 44. Respondent Castaldo has subjected his original pharmacist license to discipline for the unprofessional conduct of failing to identify the pharmacist reviewing the final drug product (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1735.3, subd. (a)). Respondent Castaldo was the pharmacist-in-charge at respondent Safeway. Four compounding worksheets for domperidone did not include the identity of the pharmacist who reviewed the final drug product.

ACCUSATION (SAFEWAY, CASTALDO, MUIR, STEPHANOS)

Stephanos

3 4

1

2

Fourteenth Cause for Discipline Unprofessional Conduct - Selling, Transferring, and Delivering Misbranded Drugs Business and Professions Code sections 4301, subdivision (o), 4169, subdivision (a)(3), Health and Safety Code section 111440

5 6

7

8

- 51. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.
- 9 10

11

12

13 14

15

16 17

18

19 20

21 22

23

24

25 26

27 28

52. Respondent Stephanos has subjected her original pharmacist license to discipline for the unprofessional conduct of selling, transferring, and delivering misbranded drugs (Bus, & Prof. Code, §§ 4301, subd. (o), 4169, subd. (a)(3); Health and Saf. Code, § 111440). Respondent Stephanos dispensed and verified 72 prescriptions for domperidone totaling approximately 7,725 capsules.

Thirteenth Cause for Discipline Unprofessional Conduct - Failure to Exercise or Implement Best Professional Judgment or Corresponding Responsibility Business and Professions Code sections 4301, 4306.5, subdivision (b)

- 53. The allegations of paragraphs 20-24 are realleged and incorporated by reference as if fully set forth.
- Respondent Stephanos has subjected her original pharmacist license to discipline 54. for the unprofessional conduct of failing to exercise or implement her best professional judgment or corresponding responsibility with regard to the dispensing or furnishing of dangerous drugs (Bus. & Prof. Code, §§ 4301, 4306.5, subd. (b)). Respondent dispensed and verified prescriptions for domperidone.

#### VIII. OTHER DISCIPLINARY CONSIDERATIONS

To determine the degree of discipline, if any, to be imposed on Original Permit 55. No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626, complainant alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60059 against Original Permit No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626. The citation assessed a civil penalty of \$1,000 against respondent

Safeway for not maintaining its location so that drugs are properly maintained, secured, and	
distributed (Bus. & Prof. Code, § 4301, subd. (o); Cal. Code Regs., tit. 16, § 1714, subd. (b)). An	
audit revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Safeway	
appealed the citation. Respondent Safeway withdrew its request for appeal on August 19, 2015,	
and paid the citation.	

Pharmacist License No. RPH 31324 issued to respondent John Vincent Castaldo, complainant alleges that on February 18, 2014, the Board issued Citation No. CI 2013 60060 against respondent Castaldo's original pharmacist license. The citation assessed a civil penalty of \$1,000 for not effectively controlling against theft or diversion of dangerous drugs, and the records for those drugs, as the pharmacist-in-charge (Cal. Code Regs., tit. 16, § 1714, subd. (d)). An audit revealed losses of over 5,000 tablets of oxycodone. On March 3, 2014, respondent Castaldo appealed the citation. Respondent Castaldo withdrew his request for appeal on August 14, 2015, and paid the citation.

#### IX. PRAYER

WHEREFORE, complainant requests that a hearing be held on the matters alleged in this accusation, and that following the hearing, the Board of Pharmacy issues a decision:

- 1. Revoking or suspending Original Permit No. PHY 52537 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;
- 2. Revoking or suspending Original Permit No. PHY 53416 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4905;
- 3. Revoking or suspending Original Permit No. PHY 51192 issued to respondent Safeway Pharmacy Inc., d.b.a. Safeway Pharmacy #4626;
- 4. Revoking or suspending Original Pharmacist License No. RPH 31324 issued to respondent John Vincent Castaldo;
- 5. Revoking or suspending Original Pharmacist License No. RPH 39228 issued to respondent Karen Lyn Muir;
  - 6. Revoking or suspending Original Pharmacist License No. RPH 61981 issued to